

REMARKS

Favorable consideration is respectfully requested in view of the foregoing amendments and the following remarks.

Claims 2, 6-17, 19-22, 24 and 25 have been cancelled without prejudice. Further, claims 26-72 have been newly added to further protect the subject matter of the newly elected claims, and claim 18 has been amended to direct to the new claims. Support for the claim amendments and new claims is readily apparent from the teachings of the specification and the original claims. Specific support can be found on pages 8-15 of the specification. Applicants wish to note that the term "non-cell binding antibody" is defined on page 8, lines 23-26, of the specification.

With regard to the Examiner's request in item 4 of the May 15, 2001 Official Action that the application be reviewed and all spelling, trademarks, and like errors be corrected, Applicants have carefully reviewed the specification and believe that no changes are needed. As stated in Applicants' response of March 5, 2001, Applicants do not believe that the term "Campath-1" is a trademark. To assist the Applicants in addressing the Examiner's concerns, Applicants request that the Examiner highlight the spelling, trademarks and like errors which form the basis of the Examiner's request.

Applicants believe that in light of the change of elected subject matter ("*A method of producing a non-cell binding antibody for inducing immunological tolerance*") and the foregoing amendments to the claims, the outstanding rejections under 35 U.S.C. §112, first and second paragraphs, 35 U.S.C. §102(b) and (e), and 35 U.S.C. §103(a) have been rendered moot and should be withdrawn.

It should be noted that based on the teachings of the specification and the knowledge in the art such as the details set forth on pages 8-12 of Applicants' March 5, 2001 response, one skilled in the art would clearly be able to practice the claimed invention without undue experimentation. Further, based on the experimental details of the production of non-cell binding antibodies or fragments thereof on pages 15-21 of the specification, Applicants also strongly believe that the present application is sufficiently detailed to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

Further, Applicants also note that no deposit of the Campath-1 antibody is necessary. As previously noted, the antibody of the examples has been described in detail (including sequence) by Reichmann et al., Nature 332:323 (1988). Thus, it is obviously known and readily available to the public or obtainable by a repeatable method. In addition, **since the claim is not limited to a particular or specific Campath-1 antibody, the deposit requirements do not apply**. Lastly, Applicants note that the Campath-1 antibody is an antibody well known to one skilled in the art as reflected by the teachings in the specification, and the references cited therein and in the Summary of References enclosed herewith. In other words, the term "Campath-1" is not merely a laboratory designation which does not clearly define the claimed product. Thus, in view of the above, Applicants respectfully request the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 112, first and second paragraph, against the term "Campath-1".

With regard to the phrase "immunological tolerance", Applicants strongly believe that phrase is well understood by one skilled in the art based on the teachings set forth in the

specification. As stated in Applicants' previous response, the phrase means a pretreatment with a given protein or molecule, irrespective of mechanism, which results in diminished capacity to respond to that or a further protein or molecule, i.e. mutant/wild type, without affecting response to unrelated antigens. This definition is consistent with the teachings of the specification and in the references cited therein. Thus, the Examiner's rejection of the phrase "inducing immunological tolerance" is clearly incorrect and improper and should be withdrawn.

With regard to the rejections under 35 U.S.C. § 102 and 103, Applicants believe that none of the cited references teach or suggest the claims of the newly elected subject matter. As the Examiner knows, to constitute anticipation of the claimed invention, the cited prior art reference must disclose each and every material element of the claim. Further, to establish a *prima facie* case of obviousness, the cited references either alone or in combination must teach or suggest the invention as a whole and include all the limitations of the claims. Here, in this case, as the Examiner has noted, the cited references (Waldmann, Crowe or Carter) *all teach maximizing the binding effectiveness of the modified antibody to Campath-1 while minimizing the immunogenic response of the modified antibody by "humanizing" modifications*. This is a completely different concept than that of the present invention which seeks to *minimize binding effectiveness of the non-cell binding antibody while maximizing the identity between the non-cell binding antibody and the therapeutic antibody to enable the non-cell binding antibody to effectively induce tolerance to the therapeutic antibody*.

It should also be noted again that the Isaacs et al. reference clearly teach, based on the disclosure and comments outlined on pages 19-21 of Applicants' March 5, 2001 response, against the use of non-cell binding molecule variants as a means for inducing tolerance.

Thus, for these reasons, Applicants believe that the outstanding rejections under 35 U.S.C. § 102 and 103, are not applicable to the presently elected claims and should be withdrawn.

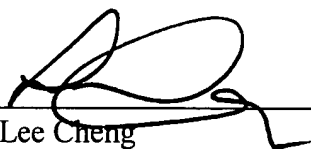
In view of the foregoing amendments and remarks, it is respectfully submitted that the Application is now in optimal form for examination and in condition for allowance. Such action is thus respectfully solicited.

If, however, the Examiner has any suggestions for expediting allowance of the application or believes that direct communication with Applicants' attorney will advance the prosecution of this case, the Examiner is invited to contact the undersigned at the telephone number below.

Respectfully submitted,

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